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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,380	03/29/2004	Iftikhar Khan	1800-000001	2606

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,380	KHAN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant uses the trademarks "Teflon" and "Dacron" to identify a material used in the claimed invention. If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. See MPEP 2173.05(u). Appropriate correction is required.

For the purposes of examination on the merits, examiner has assumed that the claimed trademarked materials include a broad class of fluoropolymers and polyesters, which are the foundation of the trademarked materials.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6, 8, 10-11, 13, 15-17, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,099,542 to Cohn et al.

In the specification and figures, Cohn discloses the device as claimed by applicant. With regard to claim 1, Cohn discloses an arteriovenous fistula with an arterial catheter 200 with a hollow tubular wall 202 forming a body, a proximal end 208 and a distal end 212 (see column 15, lines 20-28). The distal end is capable of being anastomosed to an artery wall, creating a passage from the artery to a venous catheter (see column 21, lines 44-57). Cohn further discloses a venous catheter 10 with a hollow tubular wall 12 with a distal intake end 16 and a proximal depositing end 14 (see column 15, lines 8-15). With regard to applicant's claimed cuff, Cohn discloses that in one embodiment, the catheters may comprise electrical leads 322 that perforate the vascular walls, creating an anastomosis, wherein the leads are surrounded by support elements 324 that connect to the ends of the respective catheters to create a fistula (see FIGS 14, 16, column 24, lines 13-37).

With regard to applicant's claim limitations drawn to the operability and location of deployment of the catheters (e.g., claims 6, 11, 15, 16), such limitations are held to be a recitation of the intended use of the device. It has been held that a recitation with

regard to the manner in which a claimed apparatus is intended to be employed does not differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Cohn discloses that the catheters create an AV fistula by perforating the vascular walls, thereby creating an anastomosis. Furthermore, Cohn discloses merely that the catheters, including the venous catheter, are deployed to a "desirable anatomic location" (see column 21, lines 50-57), which may include the right atrium. Since the Cohn device is capable of being deployed in the manner claimed by applicant, it meets the limitations of the claims.

With regard to claims 2-3, 10, Cohn specifically discloses that the flexible hollow catheters are deployed within a patient's vasculature to treat a patient, indicating that the catheters are made from a biocompatible material (see column 19, lines 24-30). Cohn further discloses that his catheter may be constructed of polyethylene or polyurethane, as is well-known in the art (see column 1, lines 56-67).

With regard to claim 4, Cohn discloses that the arterial catheter may be 1.5-2.5mm in diameter and about 40-150cm in length (see column 19, lines 24-30), meeting the limitations of the claim.

With regard to claims 6, 15, applicant's limitations drawn to the location of the catheter is considered by the examiner to be a statement of the intended use of the device. It has been held that a recitation with regard to the manner in which a claimed apparatus is intended to be employed does not differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Cohn discloses merely that the catheters, including the venous catheter, are deployed to a

"desirable anatomic location" (see column 21, lines 50-57), which may include deployment via the claimed catheters. Nonetheless, Cohn specifically discloses that the arterial catheter may be deployed via the brachial or femoral arteries (see column 26, lines 20-25). Since the Cohn device is capable of being deployed in the manner claimed by applicant, it meets the limitations of the claims.

With regard to claim 8, Cohn discloses that an embodiment of the invention comprises catheters that are structurally similar, indicating that the venous catheter comprises the same general size as the arterial catheter (see column 22, lines 63-65). With regard to claim 4, Cohn discloses that the arterial catheter may be 1.5-2.5mm in diameter and about 40-150cm in length (see column 19, lines 24-30), meeting the limitations of the claim.

With regard to claims 11 and 16, applicant's limitations drawn to the location of the catheter is considered by the examiner to be a statement of the intended use of the device. It has been held that a recitation with regard to the manner in which a claimed apparatus is intended to be employed does not differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Cohn discloses merely that the catheters, including the venous catheter, are deployed to a "desirable anatomic location" (see column 21, lines 50-57), which may include deployment via the claimed catheters. Furthermore, Cohn discloses that the venous catheter is deployed in a vein that is closely associated with the artery in which the arterial catheter is deployed (see column 28, lines 10-24). Since the Cohn device is

capable of being deployed in the manner claimed by applicant, it meets the limitations of the claims.

With regard to claim 13, Cohn specifically discloses that his catheter may be used for long-term hemodialysis in which a patient is connected to a dialysis machine (see column 3, lines 24-30).

With regard to claim 17, Cohn discloses the device in the claimed method and that the device catheter may be used for long-term hemodialysis in which a patient is connected to a dialysis machine. Cohn discloses that blood drains from the patient through the disclosed catheter system, filtered through the hemodialysis apparatus, and treated blood is returned to the patient (see column 3, lines 24-51). Cohn does not specifically disclose that the blood is withdrawn from the arterial catheter and returned via the venous catheter. However, it is well-known in the art of blood treatment that due to the inherent pressure differentials between arteries and veins, in order to effectively withdraw, treat, and return blood to a patient, blood is withdrawn from an arterial connection and returned to a venous connection (see, for example, US 4,486,189 to Troutner, disclosing an arterial withdrawal connection and venous return connection in a dialysis apparatus). Therefore, the Cohn disclosure meets the limitations of the claim.

With regard to claims 19 and 20, Cohn specifically discloses that the arterial catheter may be deployed via the brachial or femoral arteries (see column 26, lines 20-25) and that the venous catheter is deployed in a vein that is closely associated with the artery in which the arterial catheter is deployed (see column 28, lines 10-24). Since the

Cohn device is capable of being deployed in the manner claimed by applicant, it meets the limitations of the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,099,542 to Cohn et al.

In the specification and figures, Cohn discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of forming the cuff out of Teflon or Dacron. However, Cohn discloses that in an embodiment of his invention, the vascular perforator may comprise a microscalpel coupled with an abutment block made of various polymers (which includes Teflon, a fluoropolymer), polyurethanes, and silicon-based compositions (see column 21, lines 3-41). Examiner is considering Cohn's abutment block to correspond to applicant's claimed cuff. Cohn further discloses that it is well-known in the art to create AV fistulas out of prosthetic graft materials, which include applicant's claimed materials. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (see MPEP 2144.07). In the instant case,

Cohn discloses that a connection or cuff between the two catheters may comprise a polymer composition, suggesting the use of applicant's claimed materials.

7. Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,099,542 to Cohn et al in view of US 6,582,409 to Squitieri et al.

In the specification and figures, Cohn discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of the diameters of the catheters. Squitieri discloses an arteriovenous fistula apparatus for hemodialysis that comprises tubes implanted within the patient that are 7mm in diameter, which is within applicant's claimed range (see column 4, lines 15-17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the catheters disclosed by Cohn in the diameters disclosed by Squitieri , since Squitieri discloses that such a size is appropriate for hemodialysis fistulas (see Squitieri column 4, lines 15-17).

8. Claims 12, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,099,542 to Cohn et al in view of US 5,197,976 to Herweck et al.

In the specification and figures, Cohn discloses the apparatus substantially as claimed by applicant with the exception of one catheter being slightly smaller than the other. Herweck discloses that due to variations in artery and vein sizes within a patient, it is important to supply a surgeon implanting a vascular graft (see column 2, lines 1-10). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter system disclosed by Cohn with catheters that vary in diameter, as disclosed by Herweck, in order to accommodate the

various vessel sizes of the patient, as taught by Herweck (see Herweck, column 2, lines 1-10).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 6,022,335 Ramadan

i. Vascular access with port

b. US 2006/0064159 Porter et al

ii. Vascular access with anastomosis between vessels

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
29 August 2006